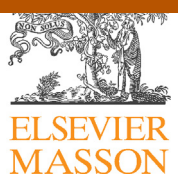
European Annals of Otorhinolaryngology, Head and Neck diseases (2013) 130, 79—85



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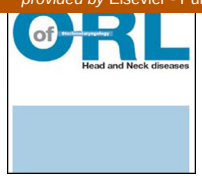

REVIEW

Implantable Doppler in monitoring free flaps: A cost-effectiveness analysis based on a systematic review of the literature

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KEYWORDS
Doppler;
Implantable;
Cost;
Effectiveness;
Vascularisation;
Free flap

Summary
Objective: The purpose of this paper is to evaluate the efficacy and cost-effectiveness of the implantable Doppler system based on the analysis of the available scientific literature and clinical and cost data available in our hospital. The results of this system are compared to those of conventional free flap monitoring methods.
Materials and methods: The literature published between 1991 and 2011 was systematically reviewed. All available cost data were collected and several simulations were performed. A retrospective assessment of the efficacy of conventional methods in our hospital was also conducted.
Results and conclusion: The implantable Doppler system is more effective than the conventional methods used to monitor free flap perfusion. The mean flap salvage rate with the implantable Doppler was 21 percentage points higher (81.4 vs. 60.4). The excess cost compared to conventional methods was about CAD 120 per patient (about EUR 94). However, this excess cost can be compensated or even reversed, depending on the initial flap salvage rate in the health facility and the type of free flap (buried vs. non-buried).

Introduction

Progress in the field of free flaps has been achieved in parallel with research concerning the optimal monitoring device. Although clinical monitoring (colour, temperature, capillary refill, pin prick, etc.) is still the gold standard (conventional monitoring), this method is highly dependent on the clinical experience of the healthcare personnel and can sometimes be difficult to implement effectively. Two types of

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doi:10.1016/j.anorl.2012.07.003

postoperative vascular problems can be observed after free flap reconstruction surgery: arterial or venous. Venous occlusion is the more frequent of these two types of problems and is detected later. Delayed detection of venous thrombosis is a serious problem, as it increases the risk of failure of free flap salvage due to the ''non-reflux'' phenomenon [1]. It has therefore become very important to develop an inexpensive, effective, rapid, and easy to use method of free flap perfusion monitoring applicable to buried and non-buried flaps. The monitoring method most closely corresponding to these criteria appears to be the implantable Doppler. Although other alternative monitoring methods will also be discussed, this study therefore essentially focuses on this technology compared to conventional monitoring methods.

Objective

The purpose of this evaluation is to determine whether use of implantable Doppler constitutes a valuable alternative to the current methods of clinical monitoring of free flap perfusion. This study assessed two endpoints: efficacy and cost.

Situation in our institution

The current mode of monitoring of free flap perfusion in our institution consists of either clinical examination of colour, temperature and capillary refill of the flap, or pin prick of the flap, when the flap is accessible, or the use of percutaneous external Doppler for buried flaps. Note that external Doppler is used as a complement to clinical examination and that it can sometimes be difficult to distinguish the flap pedicle from adjacent vessels. Flap monitoring is performed hourly for the first 24 h then every 2 h for the following 24 h and finally every 4 h for the following 7 days.

Over a 4-year period, from September 2006 to November 2010, 68 cases of head and neck free flaps were performed in our teaching hospital. Four of these 68 free flaps presented compromised perfusion (one case of vein occlusion and three cases of artery occlusion). Two of the four cases of compromised perfusion were salvaged by revision of the free flap anastomosis, corresponding to a salvage rate of 50% and a success rate (including salvage) of 95.5% (i.e. a total of three failures, including one case of intraoperative failure not related to compromised flap perfusion).

Compared to the monitoring methods currently used in our establishment, use of implantable Doppler would be considered by healthcare personnel to be more reliable to ensure effective flap monitoring. Compared to pin prick, implantable Doppler would also have the advantage of not submitting the patient to a long and uncomfortable examination.

Description of the implantable Doppler technology

Implantable Doppler is a minimally invasive technique, allowing direct and easy tissue perfusion monitoring. This technique was introduced by Swartz et al. [2] in the context of microsurgical reconstructions. The system is composed of an implantable 20 MHz ultrasound probe, mounted on a silicone cuff that can be rolled around the arterial or venous pedicle and which is connected to a portable monitor [3]. Various methods have been described to attach the cuff around the vessel, including microclips [4], sutures [5] and fibrin sealant [6], and each method provides good results. The tension exerted on the vessel by the silicone cuff is important, as an excessively tight cuff can cause obstruction to blood flow, while an excessively loose cuff can lead to false-positive results. The ultrasound probe is connected to a thin lead that is brought out through the wound. This lead is then connected to the monitor at the patient's bedside. The probe is released from the silicone cuff by pulling on the lead 5 to 10 days after the operation, when decided by the surgeon. The electrode is designed to separate from the cuff when a tension of 50 g is applied. In order to avoid accidental disconnection of the probe by pulling on the lead, the lead is connected to an extension cable, which is sutured to the patient and which connects the probe to the monitor.

Method

A review of the English and French scientific literature was conducted using PubMed as search engine and the keywords ''Doppler'' and ''implantable''. The reference period was between 1st January 1991 and 1st January 2011. All studies on efficacy, safety and learning curve of implantable Doppler were included. Studies conducted in non-human subjects were excluded. Studies using patient subgroups derived from a larger study were also excluded. The level of scientific proof classification scale for the studies reviewed was that proposed by Hailey et al. [7]. This scale classifies studies according to their methodological design from level 1 (highest) to level 9 (lowest).

Cost data were collected in collaboration with the department of human resources, the purchasing department, the financial department, the operating room and the recovery ward, the critical care and traumatology programme, the Sherbrooke University Physicians Society and the cost estimate provided by Cook Medical. The data collected concerned the cost of use of the various available technologies, their acquisition costs as well as the cost of free flap surgery following perfusion failure of the previous flap. Several cost simulations were performed as a function of implantable Doppler efficacy parameters.

Results

The PubMed search revealed 292 articles, including four reviews of the literature and 14 studies corresponding to our inclusion and exclusion criteria. According to the level of scientific proof classification scale of the studies identified, the highest score was 5, corresponding to studies for which the level of scientific proof was described as ''good to satisfactory''. The other studies were classified as 6 or 7, corresponding to studies for which the level of scientific proof was described as ''satisfactory''. Two studies were excluded, as they were based on population sub-samples derived from other studies [8,9].

The four reviews of the literature studied were not systematic and did not use any level of scientific proof criterion, leading us to consider these reviews as exclusively informative and not as studies providing conclusions that can be extrapolated to other populations, except in terms of their assessment of the ease of use and interpretation of the various technologies [1,10—12].

The studies conducted by Schusterman et al. [13], Kroll et al. [14], Hidalgo et al. [15], Nakatsuka et al. [16], Jones et al. [17], Smit et al. [18] and Spiegel and Polat [19] indicate that the free flap technique for tissue reconstruction is very effective, with success rates of about 95% or higher (including salvage procedures). However, a major limitation to this success is the risk of compromised perfusion of the free flap. According to Siemionow and Arslan [20], free flap salvage rates due to compromised perfusion were inversely proportional to the time interval between onset of ischaemia and the surgical operation. When the blood supply of a free flap is compromised and it cannot be repaired with 8 to 12 h, free flap salvage may be impossible due to ''non-reflux'' phenomena [1]. In order to overcome this problem of delayed detection of compromised free flap perfusion, it is essential to use a perfusion monitoring system. This type of system must present a certain number of characteristics in order to be used by medical personnel. In 1975, Creech and Miller [21] described what they considered to be the ideal flap perfusion monitoring system. This system had to be safe for the patients and the free flap, had to allow early detection, and had to be precise, reliable, applicable to all free flaps and easy to use by healthcare personnel.

Based on the various criteria defined by Creech and Miller [21], Smit et al. [12] conducted a review of the literature on the various free flap perfusion-monitoring techniques. Although this review of the literature did not use a particular tool to assess the quality of the studies reviewed, it provided interesting results, as the analysis was highly qualitative, providing an assessment of the applicability and ease of use of these techniques. In this review of the literature, implantable Doppler appeared to be the only technique satisfying all of the criteria defined by Creech and Miller [21]. It also appeared to be the least expensive of the alternative techniques to conventional monitoring techniques in terms of equipment and consumable items [12]. In this study, although infrared spectrography and laser Doppler are non-invasive techniques, their depth of penetration is 20 and 8 millimetres, respectively, which considerably limits their use for buried flaps. Inversely, the microdialysis technique is appropriate for buried flaps and appears to provide comparable results to those of implantable Doppler [12], but it cannot constitute a first-line solution due to its high acquisition cost and the difficulty of interpretation of the results. The two reviews of the literature conducted by Abdel-Galil and Mitchell [1,10], as well as the review by Luu and Farwell [11], led to the same conclusions as Smit et al. [12] with comparable endpoints.

In order to represent the various levels of efficacy of implantable Doppler, Table 1 indicates the true positive (detection of cases which are failures), false positive (detection of cases which are not failures), true negative (no detection of cases which are not failures), false-negative (no detection of cases which are failures) and flap salvage rates. The true-positive and false-positive rates were calculated with respect to the number of cases detected and true-negative and false-negative rates were calculated with respect to the number of cases not detected. The flap salvage rate was calculated with respect to the number of cases of compromised flap perfusion.

Most of the false-positive cases reported in older studies (before 2006) were essentially due to the learning curve associated with use of the device, such as incorrect placement or fixation of the probe, incorrect interpretation of the Doppler signal or a battery problem, or accidental displacement of the probe by pressure exerted on the lead [3,22—24]. In a more recent study, Paydar et al. [25] also reported that some of their false-positive cases were related to the learning curve of the new technology. Paydar et al. [25] and Schmulder et al. [26] reported the possibility of subjective interpretation of the venous signal by insufficiently trained healthcare personnel. A complementary test using another detection instrument should therefore be used in doubtful cases [24]. It should also be noted that, in some retrospective studies, all false-negative cases may not have been reported in writing, as they were checked by a conventional examination (colour, temperature, capillary refill, bleeding on pin prick, etc.), thereby avoiding return to the operating room. However, over time, there is a marked tendency to increased reliability of the measurements obtained with the implantable Doppler system, either due to technical improvements of implantable Doppler or improved use of this technology.

Table 1 also shows that in studies in which implantable Doppler is used not only to assess venous blood flow, but to monitor an artery or a vein, the true-positive rate appears to be fairly low and the false-negative rate is greater than 0% [3,23,24,27]. The scientific explanation for this result is that a probe implanted around an artery can immediately detect compromised arterial blood flow; however an arterial Doppler signal (i.e. probe attached to the artery) will persist for several hours after venous thrombosis. A probe implanted around the vein can detect compromised venous blood flow almost immediately and compromised arterial blood flow induces almost instantaneous loss of the venous Doppler signal. Placement of the probe around the vein therefore clearly provides a marked advantage compared to a probe placed around the artery in terms of detection of venous thromboses and can also be used to monitor arterial blood flow. This distinction is important, as more than one half of microvascular thromboses appear to be venous [28]. However, Guillemaud et al. [29] questioned this logic by reporting a lower rate of false-positive results when the probe was placed on the artery rather than the vein, but the results reported by Guillemaud et al. [29] have only a very limited scientific value, as this lower false-positive rate was not clearly demonstrated and no statistical analysis was performed.

Our systematic review of the literature identified only four comparative studies [26,30—32], corresponding to 821 operations with implantable Doppler versus 1,134 operations with a conventional monitoring method. The weighted mean of these four studies resulted in a salvage rate of 81.4% with implantable Doppler and 60.4% with conventional monitoring. However, the percentage of buried flaps was not reported in all of these studies, which biases the results with respect to conventional monitoring (i.e. the real

Table 1 Efficacy of the implantable Doppler probe.

Authors	Year	Design	Number	Success	Failure	Detected	% TP	% FP	% TN	% FN	% SR	Implantation
Swartz et al.	1994	P (6)	103	87	16	17	94.1	5.9	100	0	75	Vein
Swartz et al.	1994	P (6)	30	24	6	4	100	0	92.3	7.7	50	Artery
Kind et al.	1998	P (5)	147	131	16	20	80	20	100	0	100	Vein
French et al.	2001	R (7)	25	22	6	8	75	25	100	0	100	Vein
de la Torre et al.	2003	R (7)	118	110	8	14	57.1	42.9	100	0	87.5	Vein / artery
Oliver et al.	2005	P (6)	24	23	1	1	100	0	100	0	100	Vein
Pryor et al.	2006	R (7)	24	23	1	3	33.3	66.7	100	0	0	Vein / artery
Rosenberg et al.	2006	R (7)	20	20	1	8	12.5	87.5	100	0	100	Vein / artery
Mistry et al. [33]	2007	R (7)	4	4	0	0	—	—	100	0	—	Vein / artery
Guillemaud et al.	2008	R (7)	384	377	7	31	80.6	19.4	96.3	3.7	92	Vein / artery
Smit et al.	2010	R (5)	323	288	35	37	94.6	5.4	100	0	69	Vein
Iblher et al. [34]	2010	R (7)	52	49	3	5	100	0	100	0	66.7	—
Paydar et al.	2010	R (7)	169	150	19	21	90.5	9.5	100	0	94.7	Vein
Rozen et al.	2010	R (5)	121	111	10	11	90.9	9.1	100	0	80	Vein
Schmulder et al.	2011	R (5)	226	193	33	36	91.7	8.3	100	0	87.9	Vein

P: prospective; R: retrospective; Number: number of flaps; TP: true positive (failure detected); FP: false positive; TN: true negative; FN: false negative; SR: salvage rate. In the Design column, the level of scientific proof is indicated in parentheses [7].

performance of implantable Doppler would need to be assessed by exclusively comparing buried flaps). According to Schmulder et al. [26], the difference in salvage rates is more marked in surgical specialties in which free flaps are very often buried, such as head and neck surgery. In their study, the difference in salvage rates for this subcategory was therefore 94.12% with implantable Doppler versus 40% with conventional monitoring.

Assessing the safety of the implantable Doppler device, Rozen et al. [30] reported (without quoting their sources) the possibility of complications, such as inadequate probe placement and difficult removal of the probe. However, these authors did not encounter any of these complications in their own study. French et al. [22] and Schmulder et al. [26] also reported no complications related to the use of implantable Doppler, while Paydar et al. [25] reported three cases of vein plications in two out of 169 patients, which were related to the Doppler probe lead.

Finally, as indicated by French et al. [22], Pryor et al. [27] and Schmulder et al. [26], another important advantage of implantable Doppler for direct monitoring compared to clinical monitoring can be observed during the operation, by detecting all types of problems (blood clot and pressure on the vascular pedicle) occurring after connection of the implantable Doppler. These problems clearly represent a threat for the future survival of the free flap and can be treated immediately in the operating room.

Potential cost savings

When compromised flap perfusion is not identified in time and when revision of the flap anastomosis is unable to save the flap, another free flap must be performed, comprising harvesting of a new flap associated with complex cancer surgery. The excess cost related to this situation in our institution is presented in Table 2.

The total cost of the new operation is therefore CAD 14,053 (about EUR 10,979 for an exchange rate of 1.28 Canadian dollars for one Euro). This cost does not refer to flap anastomosis revision surgery following compromised flap perfusion, which will always be performed and implantable Doppler cannot prevent this compromised flap perfusion, but simply allows earlier detection in order to increase the free flap salvage rate.

The running costs for the various conventional flap perfusion-monitoring methods over a 5-day period are presented in Table 3.

Use of a Cook-Swartz implantable Doppler probe is associated with an excess cost of about 400 CAD (about EUR 312) compared to the other methods used in our institution. However, according to the results published in the literature, implantable Doppler allows earlier detection of compromised flap perfusion and consequently reduces the new free flap surgery rate. As shown in Table 1, the mean failure rate before re-operation can be estimated to be 9.54%. By extrapolating the results of the four studies that compared salvage rates between the implantable Doppler method (81.4%) and conventional monitoring (60.4%), systematic use of implantable Doppler would avoid the need for new free flap surgery in two out of every 100 patients. According to the studies that essentially used this system for buried flaps, implantable Doppler even appears to avoid the need for new free flap surgery in up to four or five cases per 100 [26,32]. The excess cost of CAD 400 per patient for 100

Table 2 Costs associated with free flap surgery (in Canadian dollars).

Surgery		Prolonged stay (3 days)		Administration
Personnel	Consumable items	Personnel	Consumable items	Administrative costs
Physicians: 4509 Residents: 978 Nurses: 1155 Anaesthetic nurse: 371 Anaesthetist: 1659	Equipment: 750 Infusion: 24 Cleaning: 45	Nurses: 2970	Medicinal products: 482	Logistics: 1110

Table 3 Costs of monitoring according to the method used (in Canadian dollars).[a]

Pin prick		Capillary refill		External Doppler	Implantable Doppler[b]		
Residents	Needles ($n = 54$)	Nurses	Test tubes ($n = 5$)	Nurses	Nurses	Probe	Extension cable
225	1.35	220	0.28	220	22	500	100

Note: implantable Doppler was provided free of charge, there was therefore no investment cost.
[a] Calculation based on the frequency of tests, as indicated in section 3.
[b] Based on the hypothesis that the duration of monitoring with implantable Doppler is 15 seconds compared to 5 minutes with pin prick and test tube methods. However, the frequency of tests would probably be increased with this device; it was considered to be doubled in this calculation.

patients using the implantable Doppler probe would therefore be partially compensated by avoiding two cases of redo surgery, resulting in an excess cost of CAD 120 per patient (about EUR 94 euros). In the case of oropharyngeal and pharyngeal surgery, in which flaps are buried or partially buried, a gain of four redo surgeries would lead to a saving of CAD 160 per patient (about EUR 125).

Over the last 4 years in our institution, 6% of treated cases experienced compromised flap perfusion and 3% of cases required redo free flap surgery. The flap salvage rate was therefore only 50% in oto-rhino-laryngology. By expressing these results per 100 treated patients, as in the previous paragraph, current data in our establishment therefore indicate that six patients would have experienced compromised free flap perfusion, and three of these flaps would have been saved. However, five cases would have been saved with the use of implantable Doppler (according to the salvage rate in the scientific literature of 81% with implantable Doppler). According to the cost data indicated above, the excess cost per patient would therefore be CAD 120 (about EUR 94). To achieve zero excess cost, the cost of the implantable Doppler probe and extension cable would therefore need to be reduced by 19%.

Discussion

Based on a review of the literature and the resulting cost analysis, implantable Doppler appears to ensure good quality and effective patient care, while facilitating healthcare personnel practices. Despite the variable quality of the studies identified in our review, this statement is based on the obvious convergence of the results between studies. However, randomized studies are necessary to strengthen the level of proof of the efficacy of this technology, and these studies would have to take into account the buried or non-buried nature of the flaps, as only a few of the published studies indicate the number of buried flaps (Table 4) and even fewer studies report the specific results for these flaps [24,25,32]. Failing that, it would be necessary to more clearly identify the destination of free flaps in published studies in order to determine in which subspecialties implantable Doppler would provide the greatest advantages compared to conventional monitoring. The findings of this review appear to indicate that head and neck surgery would derive the greatest benefit from the use of implantable Doppler, due to the large number of buried flaps used in this specialty. However, this opinion is only poorly supported by published studies due to the limited data available and the small number of comparative studies.

The following points must be observed to ensure optimal use of implantable Doppler:

- healthcare personnel must be adequately trained in the use of implantable Doppler;
- the use of implantable Doppler for the vein instead of the artery must be encouraged;
- when in doubt, the result indicated by the monitor must be checked by ultrasound examination or any other available and appropriate device [24];
- implantable Doppler must be mainly used to replace external Doppler and pin prick for buried or poorly accessible flaps.

Abdel-Galil and Mitchell [1] have shown that conventional monitoring methods are effective when the flap is directly visible. However, some studies [26,30] appear to show that, even for non-buried flaps, the use of implantable Doppler allows more rapid detection of compromised flap perfusion, consequently resulting in higher flap salvage rates.

Table 4 Number of free flaps with implantable Doppler monitoring.

Authors	Year	Total	H&N	Buried	Authors	Year	Total	H&N	Buried
Swartz et al.	1994	133	59	NA	Mistry et al.	2007	4	2	2
Kind et al.	1998	147	19	NA	Guillemaud et al.	2008	384	384	NA
French et al.	2001	25	2	1	Smit et al.	2010	323	39	38
de la Torre et al.	2003	118	NA	NA	Iblher et al.	2010	52	NA	NA
Oliver et al.	2005	24	NA	NA	Paydar et al.	2010	169	169	25
Pryor et al.	2006	24	24	NA	Rozen et al.	2010	121	0	0
Rosenberg et al.	2006	20	10	20	Schmulder et al.	2011	226	74	NA

H&N: head and neck; NA: not available.

From a financial point of view, it could be advantageous to use implantable Doppler when the failure rate before re-operation is greater than or equal to 6—10%. However, it must be stressed that some of the advantages of implantable Doppler were not taken into account in our cost analysis, such as the decreased psychological stress related to the flap perfusion monitoring procedure for residents and healthcare personnel, greater acceptability of this type of surgery by the patient (i.e. increased success rate) and improved comfort and quality of sleep during the patient's stay in hospital. These elements cannot be quantified in financial terms, but must be taken into account in the decision to acquire a technology such as implantable Doppler.

Conclusion

The improved free flap success rate observed during the last decade can be largely attributed to the precise and early detection of compromised flap perfusion by means of implantable Doppler. Flap salvage rates have consequently also been considerably improved, especially in the case of buried flaps. Furthermore, placement of the implantable Doppler probe does not complicate the operative procedure and is considered to be easy to use by healthcare personnel. However, the first uses of this device by medical personnel are generally associated with a learning curve that can lead to the detection of several false-positive cases. More prospective or randomized comparative studies are necessary to confirm the results of available studies and to precisely determine the differential efficacy of implantable Doppler compared to conventional monitoring methods and according to the buried or non-buried nature of the flap.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

Acknowledgements

The authors would like to thank for their advice and support, the various healthcare professionals of the CHUS, particularly Renald Lemieux, Johanne Simard, Yvan Poudrier, Linda Laverdière, Madeleine Ducharme, Bruno Lavoie, Christian Bellemare and Olivier Houle.

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